

REMARKS

In the present application, claims 1, 2 and 61-104 are pending and stand rejected in the non-final Office Action mailed March 16, 2007. Reconsideration of the present application including claims 1, 2 and 61-104 is respectfully requested.

In the Response to the Arguments, the Examiner provides reasoning as to why the arguments filed February 12, 2007, have not been found to be persuasive. With regard to the Kuslich reference, the Examiner asserts that "the cap need only be capable of being utilized with a fusion device such that is capable of engaging a through-hole therein" and that "there is nothing that would prevent this same device from engaging another hole where there were not ribs adjacent the openings only indentations in the wall of the hole." It is respectfully submitted that the cap in Kuslich is not capable of engaging a thru-hole in a fusion device that is spaced from an opening of the fusion device that is blocked by the cap. The caps in Kuslich are provided with clips 60, 148 that are located relative to the cap so they can be inserted through an opening that is spaced inwardly from the side walls of the fusion device. For example, implant 10 includes an end wall extending into the interior that defines end opening 46, and implant 12 includes ribs 146 that extend into the interior. The caps in Kuslich are thus structured so that clips 60, 148 are spaced from the side walls of implants 10, 120 toward the interior of implants 10, 120 in order to engage the structure that defines the opening that is blocked by the cap. Accordingly, Kuslich discloses a structure for the end cap that spaces clips 60, 148 away from the side walls of implants 10, 120 and into the interior of implants 10, 120. As such, the caps with clips 60, 148 do not include a structure that is capable of engaging any thru-hole of the fusion device that is spaced from the opening thereof blocked by the end cap.

With respect to the Biedermann et al. reference, the Examiner asserts that the fusion device is not positively required by the claims, and that "[f]or this reason, as long as the cap of Biedermann is capable of being utilized in the manner claimed, with any sort of fusion device, the claim language is fully met." It is respectfully submitted that it is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 9 of 22

invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The claims must not be treated as "mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning." Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al., 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate. The Office Action ignores that claimed arrangement, relationship and organization of the features in the claims, and therefore does not properly establish a *prima facie* case for rejecting the claims as being anticipated.

With respect to Applicant's remarks regarding the prongs 21, 21', noses 15 engage the V-shaped recesses 9, 10 in the ends 7, 8 of jacket 1, and Biedermann et al. teaches that the ends of prongs 21, 21' must lie outside jacket 1 since Biedermann et al. teaches that the ends of prongs 21, 21' engage the vertebral endplates and are severed to modify the angle of the vertebral endplates supported thereby. Since noses 15 lie in V-shaped recesses 9, 10 at one end of jacket 1, and prongs 21, 21' extend from ring 12 at the one end and away from the opposite end, neither edge 20 nor prongs 21, 21' are disclosed or taught as being provided with any length, structure or arrangement to engage an opening jacket 1, nor would there be any reason for one of ordinary skill in the art to modify prongs 21, 21' or edge 20 to engage any structure of jacket 1 since the ends of prongs 21, 21' are remote from jacket 1 and specifically configured to support the adjacent vertebrae, and edge 20 only extends along the interior of jacket 1 adjacent to recesses 9, 10 which are already engaged by noses 15.

Claims 1, 2, 66-68, 72 and 73 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,458,638 to Kuslich et al., or in the alternative, stand rejected as being obvious over Kuslich alone. The Examiner indicates that since the "hollow fusion device" is not positively claimed, any language referring to it only infers structure to the cap, and therefore the cap 10 of Kuslich could be used on a device like device 14 but smaller so that the prongs or clips 60 or 148 would reach to an opening

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 10 of 22

displaced from opening 142. Alternatively, the Examiner asserts that the claims could be interpreted to imply structure of the cap that is different from the cap of Kuslich, but that such a structure would have been obvious in view of Kuslich alone because the clips of Kuslich engage the interior edge of opening 142 and the through-hole runs through the interior of the body portion 122, and it would have been *prima facie* obvious to make the clips of a length to engage some other edge such as a through-hole edge to secure it to the fusion device.

It is respectfully submitted that Kuslich fails to disclose or suggest modifying the structure of the end caps disclosed therein such that the claims would read on Kuslich. Kuslich discloses clips 60, 148 that engage the interior side of the wall that defines end opening 46 of implant 10 or ribs 146 extending from sidewalls 124, 126 of implant 120. This end wall extends from the side wall of the implant toward the interior of the implant so that clips 60, 148 engage the implant between the end opening and the sidewall. If the implant in Kuslich were made smaller in size to locate a thru-hole closer to the end opening, then clips 60, 148 would merely extend into the interior of implants 10, 120, but there is no structure on the clips that would engage an opening in the side wall spaced from the end opening since clips 60, 148 are contained entirely within the interior of the implant. As discussed in previous response, it is clear that Kuslich et al. discloses and teaches an end cap having retaining clips 60, 148 that project from the body of the end cap and snap behind an endwall or ribs 146 that extend into the interior space of the implant. The endwall and ribs 146 extend into and obstruct the same opening of the implant in which the body of the cap is positioned. Thus, Kuslich discloses a cap in which clips 60, 148 are provided with a length to engage a structure located in the same opening in which the cap positioned. There is no disclosure or teaching that retaining clips 60, 148 have any length or elongate structure to engage any structure that is not located within the capped end opening and any thru-hole that is spaced from the end opening.

In addition, ribs 146 of implant 120 extend into the interior of implant 120, which offsets clips 148 away from sidewalls 124, 126 of implant 120. Implant 10 has a similar structure where trailing end opening 46 is defined by an endwall that projects into the

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Response to Non-final Office Action  
Scr. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 11 of 22

interior of implant 10 and away from the sidewalls. In order to modify clips 60 or 148 to engage a sidewall opening of the implant, the length of clips 60, 148 would have to be extended from the endwall opening into the interior of the implant, and then would have to be further modified to engage a sidewall opening. In addition to the reference failing to disclose or suggest such modifications, Kuslich teaches away from such modifications since the modifications proposed in the Office Action would result in the interior of the implant being substantially intruded upon by clips 60, 148. One of ordinary skill in the art would have no reason to make the modifications proposed in the Office Action since Kuslich teaches that the graft medium is fully applied to chamber 24 to promote fusion with the bone of the opposing vertebrae and maximizing the surface area available for grafting. See col. 7, lines 5-13 and col. 9, lines 37-40. Furthermore, with respect to implant 120, Kuslich teaches that the side walls 124, 126 do not include openings to prevent disc material from penetrating into the chamber and interfering with the bone fusion. See col. 9, lines 44-47.

In contrast, amended claim 1 recites "an occlusion body sized and shaped for blocking the opening; and an elongate anchor projecting from said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end having a lip for engaging the thru-hole, said anchor having a length between said first and second ends which reaches from said occlusion body to the thru-hole when the cap is inserted into the opening and said lip is engaged to said thru-hole when the thru-hole is spaced from the opening." Claim 1 recites a structure where the anchor is elongate and has a length to engage a thru-hole that is not the opening in which the cap is positioned. Since Kuslich does not teach or suggest an anchor with a length or structure configured as recited in claim 1, Kuslich fails to disclose or suggest claim 1 and withdrawal of this basis of the rejection is respectfully requested. Claims 2, 66-68, 72 and 73 depend from claim 1 and distinguish Kuslich at least for the reasons claim 1 does.

Claims 75-81 and 87-92 were rejected under 35 USC §102(e) as being anticipated by U.S. Patent No. 5,702,451 to Biedermann et al., or in the alternative as being obvious over Biedermann et al. alone. Biedermann et al. discloses that when ring 12 is positioned at one edge of jacket 1, prongs 21 extend axially from this edge of jacket 1 in a direction

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 12 of 22

away from the opposite edge of jacket 1. Furthermore, the Office Action asserts that "since edge (20) is designed to match the contour of the inner jacket surface, it would implicitly engage the inner jacket to the extent required by the claims." The assertion is traversed. Biedermann et al. discloses "an edge portion 20 having an outer contour which corresponds to the inner contour of the jacket 1". Biedermann et al. only discloses that the contours correspond to one another. Edge 20 and the inner contour of jacket 1 can correspond in shape but be of differing size so that there would be no engagement when ring 12 is positioned in end recesses 9, 10 of jacket 1. For example, Biedermann et al. discloses that ring 12 is identical to the ring shown in Fig. 2 (col. 2, lines 66-67) and ring 12 in Fig. 2 is disclosed as having an outer contour that corresponds to the inner contour of jacket 1. See col. 2, lines 16-18. Fig. 6 is a section view of Fig. 7 along line VI-VI. In Fig. 6, edge 20 is not shown as being aligned with any edge of the ring 12, yet both are disclosed as having a contour that corresponds to the contour of the inner surface of jacket 1. Accordingly, it is not implicit that edge 20 engages the interior of jacket 1 simply because it is disclosed as having a contour that corresponds to the contour of the inner surface of jacket 1.

Independent claim 75 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including a flat outer wall lying in a plane; and an elongate anchor projecting from said occlusion body in a direction transverse to the plane, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends from said occlusion body to the second end, wherein said length and said second end are structured and configured to engage the fusion device at a location spaced from the plane. As discussed above, Biedermann et al. reference fails to disclose or teach the elements arranged as recited in claim 75. Since noses 15 lie in the V-shaped recesses at one end of the jacket, and prongs 21, 21' extend from ring 12 at the one end and away from the opposite end, prongs 21, 21' correspond to a second end but are not disclosed or taught as being provided with any length, structure or arrangement to engage an opening in jacket 1, nor would there be any reason for one of ordinary skill in the art to modify prongs 21, 21' to engage any structure of jacket 1

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 13 of 22

since the ends of prongs 21, 21' are remote from jacket 1 and specifically configured to support the adjacent vertebrae. Furthermore, edge 20 does not provide any second end opposite a first end that is structured and configured to engage jacket 1. Edge 20 is located at the first end, which includes ring 12 that is attached to jacket 1. Therefore, independent claim 75 distinguishes Biedermann et al. and is patentable. Additionally, Applicant submits that each of claims 76-81, which either directly or indirectly depend from claim 75, are patentable for at least the reasons supporting the patentability of claim 75.

Independent claim 87 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including at least one osteogenic aperture extending therethrough; and an elongate anchor projecting from and extending transversely to said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends axially from said occlusion body to the second end, wherein said length and said second end are structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Again, the Biedermann et al. is directed to a cap where prongs 21, 21' extend axially away from jacket member 1. Edge 20 extends from end recesses 9, 10 away from the interior of jacket 1, and there are no apertures 3, 4 or other structure that is disclosed as being engaged by edge 20 that is axially spaced from ring 12. Therefore, independent claim 87 is patentable over Biedermann et al. and withdrawal of the rejection is respectfully requested. Furthermore, each of claims 88-92, which depend either directly or indirectly from claim 87, is patentable for at least the reasons supporting the patentability of independent claim 87.

Claims 75 and 77-81 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kuslich et al. alone. The Examiner asserts "that it would have been prima facie obvious to make the cap of Kuslich et al. at least partially flat on the outer surface when used on the same end as cap (18") of Kuslich for the same reasons that Kuslich does the same in that embodiment." In order to establish a prima facie case of obviousness, a reference must, amongst other requirements, teach or suggest all the claim limitations.

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 14 of 22

Manual of Patent Examining Procedure (MPEP) §2142. As discussed above with respect to claim 1, Kuslich et al. fails to teach or suggest a cap including an elongate anchor including a length and a second end structured and configured to engage the fusion device at a location spaced from the plane as recited in claim 75. Therefore, a *prima facie* case of obviousness has not been established because the reference does not teach or suggest all the claim limitations per the requirements of the MPEP § 2142. As such, Applicant respectfully requests that the obviousness rejection of claim 75 be withdrawn. Furthermore, Applicant submits that each of claims 77-81 is patentable for at least the reasons supporting the patentability of independent claim 75.

Claims 61, 62, 65, 74, 76, 87, 88, 93, and 97 were rejected under 35 USC §103(a) as being unpatentable over Kuslich et al. in view of Biedermann et al. or PCT Publication No. WO 91/06261 to Ray et al. Applicant submits that the Examiner's suggestion to modify Kuslich et al. to provide apertures in the cap is contrary to the teachings of Kuslich et al. and also would render it unsuitable for its intended purpose. Namely, leading end cap 18 covering axial opening 40 "prevents disk material from migrating through axial opening 40 into chamber 24 during insertion of the implant 10 as well as during the patient's recovery phase." (See Col. 6, Lines 57-61). Additionally, "like leading end cap 18, trailing end cap 20 prevents disk material from entering chamber 24." (See col. 7, lines 21-24). Therefore, Kuslich et al. teaches away from apertures in the end cap, and if apertures were added to leading end cap 18 or trailing end cap 20, the device of Kuslich et al. would be unsatisfactory for its intended purpose since disk material could enter chamber 24 through the cap. Thus, one of ordinary skill in the art would be led away from the modifications proposed in the Office Action.

Claim 61 depends from claim 1 and is patentable at least for the reasons claim 1 is patentable. Furthermore, claim 61 recites that the occlusion body includes osteogenic apertures, said apertures sized to permit bone ingrowth and protein ingress. As noted, Kuslich et al. teaches away from the modification to include this feature and the proposed modification would render the end cap disclosed therein unsatisfactory for its intended purpose. Therefore, withdrawal of this basis of the rejection is respectfully requested. Additionally, claims 62 and 65, which depend from claim 61, are submitted to be patentable for at least the reasons supporting the patentability of claim 61. Claim 74 depends indirectly from claim 1 and is

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 15 of 22

patentable for the reasons provided for claim 1, and is also patentable since the modification of the Kuslich et al. reference to include apertures in the leading and trailing caps would render the cap disclosed therein unsatisfactory for its intended purpose.

Claim 76 depends from claim 75 and is patentable at least for the reasons claim 75 is patentable as provided above. In addition, claim 76 recites that the occlusion body defines at least one osteogenic aperture to permit bone growth through said occlusion body. Claim 76 is further submitted to be patentable for the same underlying reasons provided above with respect to claim 61.

Claim 87 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including at least one osteogenic aperture extending therethrough; and an elongate anchor projecting from and extending transversely to said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends axially from said occlusion body to the second end, wherein said length and said second end are structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Claim 87 is submitted as patentable because Kuslich et al. teaches away from the addition of holes to the leading and trailing caps since Kuslich et al. teaches end caps that are solid to prohibit disk material from entering the interior of the fusion device. Additionally, Kuslich et al., as discussed above, fails to disclose an elongate anchor including a second end, wherein said length and said second end are structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Therefore, claim 87 is patentable and withdrawal of the rejection thereof is respectfully requested. Claims 88, 93, and 97 depend from claim 87 and are patentable at least for the reasons supporting the patentability of independent claim 87.

Claims 1, 2, 61-64, and 86 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Kuslich et al. The Examiner asserts that Biedermann et al. discloses a cap with an occlusion body including an anchor (edge 20) projecting therefrom. Furthermore, in view of the teaching of Kuslich et al., the Examiner contends that it would have been obvious to include a lip or barb on the edge

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 16 of 22

20 to hold it to the jacket member. The teachings of Biedermann et al. have been discussed above. Specifically, edge portion 20 is structured to extend such that prongs 21 and 21' engage a vertebral body. To the extent edge 20 is located along the interior of jacket 1, it is only positioned along the portions of jacket 1 that extend outwardly from the end recesses 9, 10. Accordingly, there is no thru-hole spaced from the end opening of jacket 1 for edge 20 to engage. One having ordinary skill in the art would recognize that adding a lip or barb to edge 20 would increase structure without improving or providing any function since there is no thru-hole for the lip or barb to engage, thereby increasing manufacturing costs and resultantly making the added feature undesirable. In fact, one skilled in the art may further recognize that adding a lip to edge 20 could render this structure unsatisfactory for its intended purpose, because the addition of a lip or barb could impede insertion of stop member 19 into end recesses 9, 10 of jacket 1. One of ordinary skill in the art would have no reason to make the proposed modification to the prongs 21 or edge 20 in Biedermann et al., and Applicant respectfully requests withdrawal of this basis of the rejection of claims 1, 2, 61-64, and 86.

Claims 69, 82, and 83 were rejected under 35 USC §103(a) as being unpatentable over Kuslich et al. in view of U.S. Patent Publication No. 2002/0138144 to Michelson. Claim 69 depends from claim 1, and each of claims 82 and 83 depend directly and indirectly, respectively, from independent claim 75. Based on their dependency therefrom, each is submitted as patentable, since as indicated above, the Kuslich et al. reference fails to disclose all of the claim limitations of independent claims 1 and 75. Accordingly, withdrawal of this basis of the rejection of claim claims 69, 82 and 83 is respectfully requested.

Additional reasons supporting the patentability of claims 69 and 83 exist and were argued in applicant's previous responses. "If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification!" MPEP § 2143.01. The Kuslich et al. reference discloses that body 12 is preferably formed from titanium and/or its alloys because of its noncorrosiveness and fatigue resistance. (See Col. 4, Lines 1-4). The reference further discloses that end caps 18, 20 are preferably formed of high density

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 17 of 22

polyethylene because among other characteristics it has a "slippery touch". (See Col. 7, Lines 14-16). This characteristic is valuable since the end caps may come in touch with epidural tissue which would become irritated if the surface were not "slippery". (See Col. 7, Lines 16-19). If Kuslich et al. used biodegradable caps, then the ends of titanium body 12 would become exposed, coming into contact with epidural tissue and causing irritation thereof, making the device unsatisfactory for its intended purposes. Therefore, Applicant respectfully requests withdrawal of this rejection of claims 69 and 83 for these additional reasons.

Claims 82 and 83 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Michelson (U.S. 2002/0138144). Each of claims 82 and 83 depends directly and indirectly, respectively, from independent claim 75. Based on their dependency therefrom, each is submitted as patentable, since as indicated above, Biedermann et al. fails to disclose all of the claim limitations of independent claim 75.

Claim 94 was rejected under 35 USC §103(a) as being unpatentable over Kuslich et al., Biedermann et al., and Ray as applied to claims 61, 62, 65, 74, 76, 87, 88, 93, and 97 in further view of Michelson (2002/0138144). Claim 94 depends directly from independent claim 87 and is submitted as patentable for at least the reasons submitted herein supporting the patentability of independent claim 87. Additionally supporting the patentability of claim 94, as already submitted herein, is that Kuslich et al. and Biedermann et al. teach away from biodegradable end caps. Applicant therefore submits claim 94 is patentable and respectfully requests withdrawal of this ground of rejection.

Claim 70 was rejected under 35 USC §103(a) as being unpatentable over Kuslich in view of U.S. Patent No. 6,605,089 to Michelson. Claim 70 depends directly from independent claim 1 and is patentable for at least the reasons supporting the patentability of independent claim 1 as discussed above.

Claim 84 was rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Michelson (U.S. Patent No. 6,605,089). Claim 84 depends from independent claim 75 is patentable at least for the reasons claim 75 is patentable as discussed above.

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 18 of 22

Claims 71 and 85 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. and Michelson (6,605,089) as applied to claim 84 above in further view of French Patent No. 2,710,519 to Robine. Claim 71 depends from claim 1, and claim 85 depends from claim 84. Claims 71 and 85 are patentable for the same reasons supporting the patentability of claims 1 and 84 and Applicant respectfully requests withdrawal of the rejection thereof. Furthermore, there is no reason to provide member 19 of Biedermann et al. with a threaded hole for an insertion instrument. As discussed above, member 19 is positioned on the ends of jacket 1, and extends from jacket 1 to contact and support a vertebral endplate. Member 19 must be pre-loaded on the end of jacket 1 before jacket 1 is positioned between the vertebrae, and since prongs 21, 21' extend away from jacket 1 when positioned thereon, prongs 21, 21' can be readily grasped to facilitate insertion of member 19 onto jacket 1. Providing a threaded hole in member 19 provides no advantage nor would it aid insertion of member 19 since member 19 can be readily placed on the end of jacket 1 before it is installed. The threaded hole on the end cap of the present invention, on the other hand, facilitates insertion and engagement of the end cap to a fusion device that is already positioned between vertebrae. The modification to Biedermann et al. proposed in the Office Action to provide a threaded hole in member 19 increases cost and complexity of member 19 without any corresponding benefit since member 19 cannot be positioned on jacket 1 after jacket 1 is installed in the patient. Accordingly, withdrawal of the rejection to claims 71 and 85 is respectfully requested.

Claim 96 was rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Robine. Claim 96 depends from claim 87, which is patentable for the reasons provided above. Furthermore, as discussed above with respect to claims 71 and 85, there is no reason for one of ordinary skill in the art to modify Biedermann in the manner proposed in the Office Action since no corresponding benefit or advantage is provided by the modification. Therefore, withdrawal of this basis of the rejection of claim 96 is respectfully requested.

Claim 95 was rejected under 35 USC §103(a) as being unpatentable over Kuslich et al., Biedermann et al., and Ray as applied to 61, 62, 65, 74, 76, 87, 88, 93, and 97

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 19 of 22

above, and in further view of Michelson (U.S. Patent No. 6,605,089). Claim 95 directly depends from claim 87 which is patentable for reasons asserted herein. Thus, claim 95 is submitted as patentable at least for the reasons supporting the patentability of independent claim 87 and withdrawal of this basis of the rejection is respectfully requested.

Claims 98-103 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Michelson (U.S. Patent No. 6,650,089). Independent claim 98 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body being composed of a porous material; and an elongate anchor projecting from and extending transversely to said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends axially from said occlusion body to the second end, wherein said length and said second end are structured and configured to engage the fusion device at a location axially spaced from said occlusion body.

The prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2142. As discussed above, the Biedermann et al. reference does not disclose, suggest or teach a cap including an elongate anchor with a length and a second end structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Instead, edge 20 and prongs 21, 21' are structured and configured to extend axially away from jacket member 1 (fusion device) to engage a vertebral body, and edge 20 lies at the same end of jacket 1 engaged by noses 15. Thus, Applicant contends a *prima facie* case of obviousness in regard to claims 98-103 has not been made. Furthermore, one of ordinary skill in the art would find no reason to modify Biedermann et al. to include a second end structured and configured to engage the fusion device at a location axially spaced from said occlusion body as proposed in the Office Action. Biedermann et al. teaches that prongs 21, 21' extend away from jacket 1, and any lips or barbs on edge 20 provide no advantage or function since edge 20 lies in the same end as noses 15 and ring 12, and noses 15 already are provided to secure member 19 to jacket 1. One of ordinary skill in the art also would

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 20 of 22

not reverse member 19 so that prongs 21, 21' extend into jacket 1 since such a modification changes the principal of operation of the device in Biedermann et al. As discussed above, the ends of prongs 21, 21' engage the vertebral endplates, are sized to extend away from jacket 1 to provide the proper spacing between vertebrae, and to provide the desired angulation between the vertebral endplates. Reversal of the positioning of member 19 on jacket 1 eliminates all of these functions of member 19, while providing no additional or other advantage. Since there is no reason to modify Biedermann et al. as suggested in the Office Action, a prima facie case for rejecting claims 98-103 has not been established and withdrawal of the rejection of claims 98-103 is respectfully requested.

Claim 104 was rejected under 35 USC §103(a) as being unpatentable over Biedermann and Michelson as applied to claims 98-103 and further in view of Kuslich et al. Claim 104 is submitted as patentable at least for the reasons submitted supporting the patentability of claims 98-103. Furthermore, as discussed above, Applicant contends that one having ordinary skill in the art would have no reason to add lips or barbs to edge 20 or prongs 21, 21' as such addition would increase structural complexity without gaining a structural advantage. Biedermann teaches that prongs 21, 21' extend away from jacket 1, and, as discussed above, any lips or barbs on edge 20 provide no advantage or function. One of ordinary skill in the art also would not reverse member 19 so that prongs 21, 21' extend into jacket 1 since such a modification changes the principal of operation of the device in Biedermann et al. As discussed above, the ends of prongs 21, 21' engage the vertebral endplates, are sized to extend away from jacket 1 to provide the proper spacing between vertebrae, and to provide the desired angulation between the vertebral endplates. Reversal of the positioning of member 19 on jacket 1 eliminates all of these functions of member 19, while providing no additional or other advantage. Accordingly, one of ordinary skill in the art would have no reason to modify Biedermann et al. as proposed in the Office Action. Withdrawal of this basis of the rejection of claim 104 is respectfully requested.

Claims 71, 85 and 96 were rejected under 35 USC §103(a) as being unpatentable over Kuslich et al. and Michelson (U.S. Patent No. 6,605,089) as applied to claim 70

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 21 of 22

above, and further in view of Robine. Each of claims 71, 85, and 96 is submitted as patentable at least for the reasons supporting the patentability of each underlying base claim 1, 75, and 87 as discussed above.

Additionally, the prima facie case for rejecting these claims was traversed in the previous response. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." Manual of Patent Examining Procedure (MPEP) § 2141.02. Moreover, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." Manual of Patent Examining Procedure (MPEP) § 2143.01. As submitted above, Kuslich et al. is directed to end caps that are structured to keep disk material from migrating into chamber 24 during insertion of the implant as well as during the recovery phase. (See Col. 6, Lines 58-61; Col. 7, Lines 22-24). Adding a threaded hole to the end caps of Kuslich et al. is contrary to the teachings in Kuslich et al. since disk material could migrate into the chamber through the threaded hole. Therefore, Applicant submits that each of claims 71, 85, and 96 is patentable over the Kuslich and Michelson (U.S. Patent No. 6,605,089) in view of Robine, and withdrawal of this basis of the rejection is respectfully requested.

Reconsideration and allowance of the present application as amended and including claims 1-2 and 61-104 is hereby respectfully solicited. The Examiner is welcome to contact the undersigned to resolve any outstanding issue with regard to the present application.

Respectfully submitted

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Response to Non-final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 22 of 22